

REMARKS/ARGUMENTS

Amendment to the Specification

In the specification, the paragraphs [0047] and [0059] have been amended to correct minor editorial problems.

Amendment to the Claims

Claims 1-48 are currently in the application. Claims 6, 41-44 and 46 are cancelled without prejudice. New Claim 49-54 added. Claims 12, 18, 23-27, 31-35, 37-43, 45, and 47-48 are presently withdrawn.

Claims 2, 5, 7, and 13 are amended.

Claims 2 and 13 are amended wherein the retracting means retracts the injection needle from its second position to a third position within the housing.

Claim 5 is amended to incorporate the limitation of Claim 6, to further provide the device with a means for retracting the injection needle from its second position to a third position within the housing. Claim 6 has been cancelled.

Claim 7 is amended to delete the redundant limitation.

New Claims 49, 50, 51, 52, 53 and 54 are dependent from Claims 1, 5, 9, 15, 19 and 29, respectively, and each provides that the device further comprises a means for attaching the base of the self-contained device for semi-permanent attachment to the skin of the patient, the attaching means being configured wherein during the pumping step, a person is not required to hold the device.

Claim Rejections under 35 USC §103

Claim 1-11, 13-17, 19-22, and 28-29 are rejected as obvious over Pike (US 4031889) in view of Miskinyar (US 5527287).

The Examiner's rejection alleges that Pike discloses a hypodermic syringe that is driven by pneumatic (50,52) pressure, a reservoir (81), a housing, an injection needle (89), a means for liquid communication between the reservoir and the injection needle (77), and a means for pumping the medicament from the reservoir to the injection end of the needle (72, 82, 61) [and a reservoir urging means for moving the reservoir into liquid communication with the inlet of the

injection needle (60,82,72,86)], a means for retracting and a means for automatically and sequentially (sic), but fails to teach a means for a means for inserting the injection needle to its second position.

The Examiner's rejection also alleges that Miskinyar discloses a preloaded automatic disposable syringe with a means for inserting the injection needle to its second position (224) as well as showing the level of skill in the art with regards to needle size and length (Column 1, line 47-52).

The Examiner concluded that, at the time of the invention, it would have been obvious for one of ordinary skill in the art to combine the device of Pike with the teachings of Miskinyar because Miskinyar teaches a spring that holds the reservoir and needle in the retracted position (column 7, lines 20-28) thus avoiding accidental pricking before and after injection.

Applicant traverses.

i. the Examiner has mischaracterized the prior art references in the rejection

The Examiner states that Pike discloses "a means for retracting", which Applicant assumes is meant as "a means for retracting the needle". Applicant can find no mention, teaching or suggestion in the description or figures of Pike of a device or other means for retracting the needle after insertion in the tissue and injection of the medicament, as provided in several of Applicant's claims. Pike does not disclose a retracting means.

The Examiner also states that Miskinyar teaches a spring that holds the reservoir and needle in the retracted position thus avoiding accidental pricking before and after rejection". Miskinyar describes several retractor means, namely spring 102 in Figures 8 and 9, spring 152 in Figure 10, and spring 224 in Figure 12, which provide a means for maintaining the ampoule and needle in a retracted position. However, as can plainly be seen in the figures and as described in Miskinyar, the "retracted position" is the position of the ampoule and needle prior to insertion of the needle and injection of the medication. The "retractor spring" of Miskinyar does not retract the needle after it has been inserted into the patient; rather, the "retractor spring" prevents the needle from pre-mature or accidental extension outside of the housing. Miskinyar does not disclose or suggest a means for retracting the injection needle from the extended second position after completing the injection of the medicament.

Consequently, the rejection is entirely based on incorrect interpretation of the two prior art references.

ii. the Examiner fails to state a *prima facie* obviousness rejection

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Either the reference must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972,973 (Bd. Pat. App. & Inter. 1985).

The Applicant believes that the Examiner has failed to meet his initial burden to provide some suggestion of the desirability of doing what the inventor has done.

Pike teaches a hand-held hypodermic syringe that is powered using compressed gas to insert a hypodermic needle from within the syringe into the patient, and to inject the medication through the needle intramuscularly and subcutaneously. Pike teaches an automatically controlled aspiration in the event the inserted hypodermic needle punctures a blood vessel and aspirates blood back into the medication reservoir.

Miskinyar teaches a disposable device that uses spring force to automatically insert a needle from within the device into the patient, and to inject the medication through the needle

intramuscularly and subcutaneously. As above explained, Miskinyar does not teach or suggest the retracting means as defined and claimed by Applicant; rather, the retracted position of Miskinyar is the position of the ampoule and needle prior to insertion of the needle and injection of the medication. While no similar spring means is disclosed in Pike, there is no specific suggestion or teaching of a need for holding the injection assembly 70 with needle 89 in a so-called “retracted position” of Miskinyar, prior to insertion of the needle into the patient.

The Examiner’s rejection includes the bare conclusion that “at the time of the invention, it would have been obvious for one of ordinary skill in the art to combine the device of Pike with the teachings of Miskinyar because Miskinyar teaches a spring that holds the reservoir and needle in the retracted position thus avoiding accidental pricking before and after rejection”. However, the Examiner has not identified in either reference, a source of any motivation, suggestion or teaching for incorporating the so-called “retractor spring” of Miskinyar into the device of Pike.

Finally, Applicant points out that neither Pike nor Miskinyar disclose the retracting means described by Applicant, which retracts the needle from its second position disposed within the tissue of the patient, to a third position within the housing. As the “retracting spring” was the reason given for finding the combination obvious, the *prima facie* obviousness rejection must fail.

iii. the alleged combination of references fails to disclose every element of Applicant’s claims

Even if, just for the sake of argument, the two references were to be combined, neither reference teaches any one of the following features of the Applicant’s claimed invention:

1. the injection needle having an outside diameter greater than 0.20 mm and less than about 0.38 mm, for painlessly inserting the needle into the tissue of a patient.
2. pumping of the medicament at a rate sufficiently slow to effect painless injection of the medicament into the tissue of the patient, and specifically a rate between about 0.5 $\mu\text{L/s}$ to about 20 $\mu\text{L/s}$.
3. a means for retracting the injection needle from its second position to a third position within the housing.

4. a means for automatically and sequentially extending the needle, injecting the medicament, and retracting the needle into the housing.

5. a means for attaching the base of the self-contained device for semi-permanent attachment to the skin of the patient, the attaching means being configured wherein during the pumping step, a person is not required to hold the device.

Reinstatement of Withdrawn Claims

Applicant respectfully requests reinstatement of withdrawn Claims 12, 18, 23-27 to a device, which are either dependent from pending claims which Applicant believes are allowable, or which include elements or limitations that the Applicant asserts are patentable over the cited references.

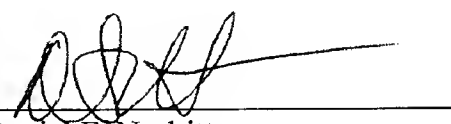
Conclusion

Applicant believes a complete response to the office action has been provided, and that the present invention as claimed clearly distinguishes the teachings of the prior art of record. Applicant requests a prompt allowance of all claims.

Respectfully submitted,

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